DEC 1 0 2009

K093714

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

MEDISON CO., LTD. 1003, Daechi-dong, Gangnam-gu, Seoul 135-280, Korea

Contact Person:

Mr. Kyung-Am, Shim Regulatory Affairs Manager

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Data Prepared: September 7, 2009

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

SONOACE X8 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Identification of the predicate or legally marketed device:

K063580, SONOACE X8 Diagnostic Ultrasound System K092159, ACCUVIX V20 Diagnostic Ultrasound System

4. Device Description:

The SONOACE X8 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, M mode, Color Doppler mode, Power Doppler mode, PW Spectral Doppler, CW Spectral Doppler mode, and Tissue Doppler Image mode on the LCD display. It also provides the 3D/4D imaging mode using the 3D/4D probe in the Mechanical scan mode.

The SONOACE X8 has real time acoustic output display with two basic indices, a

mechanical index and a thermal index, which are both automatically displayed. The system also provides for the measurement of anatomical structures and for analysis packages that provide information used for clinical diagnostic purposes by competent health care professionals.

The SONOACE X8 has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993-1, Biocompatibility

5. Intended Uses:

The SONOACE X8 system and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include:

General, abdomen, obstetrics, gynecology, vascular, extremity, pediatric, cardiac, breast, urology, neonatal cephalic, trans-esophageal. and etc.

6. Technological Characteristics:

The SONOACE X8 is substantially equivalent to the SONOACE X8 Diagnostic Ultrasound System, cleared via K063580, and the ACCUVIX V20 Diagnostic Ultrasound System, cleared via K092159. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 10903 New Hampshire Avenue Document Mail Center - WO66-G609 Silver Spring, MD 20993-0002

Medison Co., Ltd. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

DEC 1 0 2009

Re: K093714

Trade/Device Name: SONOACE X8 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYO, IYN, and ITX

Dated: December 1, 2009 Received: December 2, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOACE X8 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3D2-6ET	<u>C2-5EP</u>	NEV4-9ES	<u>P2-4AA</u>
3D4-8EK	<u>C2-8</u>	<u>HL5-12ED</u>	<u>P2-4AH</u>
<u>3D4-8ET</u>	<u>C3-7EP</u>	<u>L4-7EL</u>	<u>P3-5AC</u>
3D4-9ES	<u>C4-9/10ED</u>	L5-12/50EP	<u>P3-7AC</u>
<u>3D5-9EK</u>	ER4-9/10ED	<u>L5-12EC</u>	<u>CW 2.0</u>
3DC2-6	EV4-9/10ED	<u>L5-12EP</u>	CW 4.0
<u>C2-5EL</u>	NER4-9ES	<u>MPT4-7</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,

∕Janine M. Morris

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Section 1.3 INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.:

093714

Device Name: SONOACE X8 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application			Mo	de of Op	eration (*inc	ludes simultaneo	us B-mode)
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic				l			
	Fetal (See Note 3)	P	P	P	P	P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P	P	P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	Р	P	P	P	P	Note 1	Note 2,4,5,6,7,8,9
	Small Organ (See Note 5)	Р	P	Ρ.		P	Note 1	Note 2,5,6,8,9
	Neonatal Cephalic	Р	P	Ρ.	P	Р	Note 1	
	Adult Cephalic	Р	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal	P	P	P		P	Note 1	Note 2, 3, 8
	Trans-vaginal	Р	P	P		P	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	N	N	N	N	N	Note 1	Note 4, 7
	Musculo-skel. (Convent.)	Р	P	P		P	Note 1	Note 2,5,6,8,9
	Musculo-skel. (Superfic.)	Р	P	P		P	Note 1	Note 2,5,6,8,9
	Intra-luminal					-		
	Other (spec.)			-				
	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note 1	Note 4, 7
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P	P	P	Note 1	Note 5, 6, 9
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

3D2-6ET for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

С	linical Application						udes simultaneo	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							-
	Fetal (See Note 3)	Р	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)				-			
Fetal Imaging	Laparoscopic							
& Other	Pediatric	Р	Р	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)						1	
	Neonatal Cephalic							
	Adult Cephalic							· · · · · · · · · · · · · · · · · · ·
	Trans-rectal							
	Trans-vaginal							·-··
	Trans-urethral							
	Trans-esoph. (non-Cardiac)						-	
	Musculo-skel. (Convent.)			i				· · · · · · · · · · · · · · · · · · ·
	Musculo-skel. (Superfic.)							····
	Intra-luminal							<u> </u>
	Other (spec.)							
	Cardiac Adult		-					
Cardiac	Cardiac Pediatric							····
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler, B/Power Doppler, B/Power Doppler, B/Color Doppl

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH,	Office of	Device	Evaluation	(ODE)
Prescription				, ,

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

3D4-8EK for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application						udes simultaneo	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)	<u> </u>						
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic			1			******	
-	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult						1	
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

3D4-8ET for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	inical Application			-			udes simultaneo	
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
,	Fetal (See Note 3)	Р	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic					,		- · · ·
& Other	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							·
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)						1	
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral	Peripheral vessel							, , , , , , , , , , , , , , , , , , ,
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21, EFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

3D4-9ES for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cl	linical Application			Mo	de of Ope	ration (*incl	udes simultaneo	us B-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging	Fetal (See Note 3) Abdominal Intra-operative (See Note 6) Intra-operative (Neuro.) Laparoscopic						·	
& Other	Pediatric Small Organ (See Note 5) Neonatal Cephalic Adult Cephalic							
	Trans-rectal Trans-vaginal Trans-urethral	P P	P P	P P		P P	Note 1 Note 1	Notes 2, 8 Notes 2, 8
	Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal Other (spec.)							
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (Cardiac) Other (spec.)							
Peripheral Vessel	Peripheral vessel Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

3D5-9EK for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	linical Application			M	ode of O	peration (*inc	cludes simultaneou	s B-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic						["	
, -	Fetal (See Note 3) Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)	1						
Fetal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (See Note 5)	1			•		· · · · · · · · · · · · · · · · · · ·	
	Neonatal Cephalic							
	Adult Cephalic	1						.
	Trans-rectal	Р	P	Р		P	Note 1	Notes 2, 8
	Trans-vaginal	Р	P	P		P	Note 1	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	1						
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal	1						
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)			1				
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

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Prescription	n Use (Per 2	1 CFR	801.109)
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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

3DC2-6 for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
<u>-</u> -	Fetal (See Note 3)	N	N	N		N	Note 1	Notes 2, 7, 8		
	Abdominal	N	N	N		N	Note 1	Notes 2, 7, 8		
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic						-			
& Other	Pediatric	N	N	N		N	Note 1	Notes 2, 7, 8		
	Small Organ (See Note 5)									
	Neonatal Cephalic									
	Adult Cephalic							· · · · · · · · · · · · · · · · · · ·		
	Trans-rectal							···········		
	Trans-vaginal						· · · · · · · · · · · · · · · · · · ·			
	Trans-urethral									
	Trans-esoph. (non-Cardiac)				-					
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (Cardiac)					-				
	Other (spec.)									
Peripheral	Peripheral vessel									
Vessel	Other (spec.)									

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppl

- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

C2-5EL for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic						<u> </u>			
	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8		
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8		
	Intra-operative (See Note 6)			-						
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic									
& Other	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8		
	Small Organ (See Note 5)				,					
	Neonatal Cephalic				*					
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal	1				*				
	Trans-urethral									
	Trans-esoph. (non-Cardiac)									
	Musculo-skel. (Convent.)	i								
	Musculo-skel. (Superfic.)									
	Intra-luminal	1					-			
	Other (spec.)	1								
-	Cardiac Adult			i			1			
Cardiac	Cardiac Pediatric							·		
	Trans-esophageal (Cardiac)					-				
	Other (spec.)									
Peripheral	Peripheral vessel						-			
Vessel	Other (spec.)									

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 GFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ______

510(k) No.:

Device Name: C2-5EP for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
	Fetal (See Note 3)	N	N	N		N	Note 1	Notes 2, 7, 8		
	Abdominal	N	N	N		N	Note 1	Notes 2, 7, 8		
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic									
& Other	Pediatric	N	N	N		N	Note 1	Notes 2, 7, 8		
	Small Organ (See Note 5)									
	Neonatal Cephalic						-			
	Adult Cephalic							 .		
	Trans-rectal									
	Trans-vaginal							· • · · · · · · · · · · · · · · · · · ·		
	Trans-urethral			`						
	Trans-esoph. (non-Cardiac)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)	İ		1				щ_		
	Intra-luminal									
	Other (spec.)	1.					-	 		
1.11	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (Cardiac)	1								
	Other (spec.)									
Peripheral	Peripheral vessel							·-·		
Vessel	Other (spec.)									

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name: C2-8 for us

C2-8 for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic						ļ				
	Fetal (See Note 3)	N	N	N		N	Note 1	Notes 2, 7, 8			
	Abdominal	N	N	N		N	Note 1	Notes 2, 7, 8			
	Intra-operative (See Note 6)		<u> </u>	1							
	Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic										
& Other	Pediatric	N	N	N		N	Note 1	Notes 2, 7, 8			
	Small Organ (See Note 5)										
	Neonatal Cephalic	Π									
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Cardiac)										
	Musculo-skel. (Convent.)			-							
	Musculo-skel. (Superfic.)										
	Intra-luminal										
	Other (spec.)	'									
. "	Cardiac Adult					•					
Cardiac	Cardiac Pediatric				, ,						
	Trans-esophageal (Cardiac)										
	Other (spec.)										
Peripheral	Peripheral vessel		`								
Vessel	Other (spec.)										

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name: C3-7EP for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	linical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic							1		
	Fetal (See Note 3)	P	P	Р		P	Note 1	Notes 2, 7, 8		
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8		
	Intra-operative (See Note 6)									
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic									
& Other	Pediatric	Р	P	P		P	Note 1	Notes 2, 7, 8		
	Small Organ (See Note 5)							· · · · · · · · · · · · · · · · · · ·		
	Neonatal Cephalic							 		
	Adult Cephalic									
	Trans-rectal						· · · · · · · · · · · · · · · · · · ·	.		
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Cardiac)									
	Musculo-skel. (Convent.)	1						·		
	Musculo-skel. (Superfic.)			-						
	Intra-luminal									
	Other (spec.)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esophageal (Cardiac)					,				
	Other (spec.)									
Peripheral	Peripheral vessel					-				
Vessel	Other (spec.)	1						· · · · · · · · · · · · · · · · · · ·		

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler, B/Power Doppler, B/Color Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use/(Per 21 CFR)801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name: C4-9/10ED for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application						es simultaneous B	-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	T						
	Fetal (See Note 3)	P	Р	P		_ P	Note 1	Note 2, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 8
	Intra-operative (See Note 6)					-		
	Intra-operative (Neuro.)							•
Fetal Imaging	Laparoscopic	1		··	-			
& Other	Pediatric	P	P	P		P	Note 1	Note 2, 8
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 8
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2, 8
	Adult Cephalic		П					
	Trans-rectal			-				<u> </u>
	Trans-vaginal	1 -						-
	Trans-urethral							······································
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)		11					
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	1						
	Trans-esophageal (Cardiac)	1						
	Other (spec.)			_				
Peripheral	Peripheral vessel	Р	Р	P		Р	Note 1	Note 2, 8
Vessel	Other (spec.)	T						1.0.0 2, 0

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name: ER4-9/10ED for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal (See Note 3) Abdominal					ı					
	Intra-operative (See Note 6)	1									
	Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic	1									
& Other	Pediatric										
	Small Organ (See Note 5)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal	P	P	P		P	Note 1	Note 2, 8			
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 8			
	Trans-urethral										
	Trans-esoph. (non-Cardiac)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.)						1				
	Intra-luminal										
	Other (spec.)										
	Cardiac Adult										
Cardiac	Cardiac Pediatric							•			
	Trans-esophageal (Cardiac)	L									
	Other (spec.)										
Peripheral	Peripheral vessel										
Vessel	Other (spec.)										

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 £RR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices,

510(k) Number 1013 (14

510(k) No.:

Device Name: EV4-9/10ED for

EV4-9/10ED for use with SONOACE X8

C	linical Application			Mod	e of Opera	tion (*include	es simultaneous B	-mode)
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							1111
	Fetal (See Note 3)							
	Abdominal							· · · · · · · · · · · · · · · · · · ·
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)			<u>-</u>				
Fetal Imaging	Laparoscopic							
& Other	Pediatric		\Box					
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal		1					
	Other (spec.)							
-	Cardiac Adult	1						
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	1						
	Other (spec.)	T						
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR)801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

23 field Mumber

510(k) No.:

Device Name: NER4-9ES for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application						es simultaneous B	
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic		•					
	Fetal (See Note 3) Abdominal Intra-operative (See Note 6) Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic Pediatric Small Organ (See Note 5)							
	Neonatal Cephalic Adult Cephalic Trans-rectal	P	P	P		P	Note 1	Note 2, 8
	Trans-vaginal Trans-urethral	P	P	P		P	Note 1	Note 2, 8
	Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.) Musculo-skel. (Superfic.) Intra-luminal							
Cardiac	Other (spec.) Cardiac Adult Cardiac Pediatric Trans-esophageal (Cardiac) Other (spec.)							
Peripheral Vessel	Peripheral vessel Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number 1043'114

510(k) No.:

Device Name: NEV4-9ES for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal (See Note 3) Abdominal Intra-operative (See Note 6) Intra-operative (Neuro.) Laparoscopic Pediatric Small Organ (See Note 5) Neonatal Cephalic									
	Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.) Musculo-skel. (Superfic.)	P P	PP	P P		P P	Note 1 Note 1	Note 2, 8 Note 2, 8		
	Intra-luminal Other (spec.)									
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (Cardiac) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)									

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Device

510(k) No.:

Device Name:

HL5-12ED for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cl	linical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
,	Fetal (See Note 3)										
	Abdominal					li .					
	Intra-operative (See Note 6)										
	Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic										
& Other	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9			
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9			
	Neonatal Cephalic							.			
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal							-			
	Trans-urethral										
	Trans-esoph. (non-Cardiac)										
	Musculo-skel. (Convent.)	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 9			
	Musculo-skel. (Superfic.)	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 9			
	Intra-luminal										
	Other (spec.)										
	Cardiac Adult	1		-			-1				
Cardiac	Cardiac Pediatric										
	Trans-esophageal (Cardiac)							· ·			
	Other (spec.)										
Peripheral	Peripheral vessel	P	Р	P		P	Note 1	Note 2, 5, 6, 7, 9			
Vessel	Other (spec.)										

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Vse (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

L4-7EL for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
Fetal Imaging	Fetal (See Note 3) Abdominal Intra-operative (See Note 6) Intra-operative (Neuro.) Laparoscopic									
& Other	Pediatric Small Organ (See Note 5)	P P	P	P P		P P	Note 1	Note 2, 5, 6, 7, 9 Note 2, 5, 6, 7, 9		
	Neonatal Cephalic Adult Cephalic Trans-rectal							2,0,0,7,7		
	Trans-vaginal Trans-urethral									
	Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9		
	Musculo-skel. (Superfic.) Intra-luminal Other (spec.)	P	P	P		Р	Note 1	Note 2, 5, 6, 7, 9		
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (Cardiac) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)	P	P	Р		P	Note 1	Note 2, 5, 6, 7, 9		

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number___

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

510(k) No.:

Intended Use:

Device Name: L5-12/50EP f

L5-12/50EP for use with SONOACE X8

Clinical Application Mode of Operation (*includes simultaneous B-mode) General Specific M **PWD CWD** Color Combined* Other (Track I only) (Tracks I & III) Doppler* (Spec.) (Spec.) Ophthalmic Ophthalmic Fetal (See Note 3) Abdominal Intra-operative (See Note 6) Intra-operative (Neuro.) Fetal Imaging Laparoscopic & Other Pediatric P P P P Note 2, 5, 6, 7, 9 Note 1 Small Organ (See Note 5) P P P P Note 1 Note 2, 5, 6, 7, 9 Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.) P P P P Note 1 Note 2, 5, 6, 7, 9

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

P

P

P

P

P

P

P

Note 1

Note 1

Note 2, 5, 6, 7, 9

Note 2, 5, 6, 7, 9

Additional Comments:

Cardiac

Peripheral

Vessel

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler, PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Р

- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)

Musculo-skel. (Superfic.)

Trans-esophageal (Cardiac)

Intra-luminal
Other (spec.)
Cardiac Adult

Other (spec.)

Other (spec.)

Cardiac Pediatric

Peripheral vessel

- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number < CM 3/14

510(k) No.:

Device Name: L5-12EC for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic					"-					
	Fetal (See Note 3) Abdominal										
	Intra-operative (See Note 6)										
	Intra-operative (Neuro.)										
Fetal Imaging	Laparoscopic										
& Other	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9			
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9			
	Neonatal Cephalic										
	Adult Cephalic							···			
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral					·					
	Trans-esoph. (non-Cardiac)										
	Musculo-skel. (Convent.)	Р	P	P		Р	Note 1	Note 2, 5, 6, 7, 9			
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9			
	Intra-luminal							•			
	Other (spec.)										
	Cardiac Adult				ĺ						
Cardiac	Cardiac Pediatric										
	Trans-esophageal (Cardiac)										
	Other (spec.)										
Peripheral	Peripheral vessel	P	. Р	P		P	Note 1	Note 2, 5, 6, 7, 9			
Vessel	Other (spec.)							/			

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name: L5-12EP for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation (*includes simultaneous B-mode) B M PWD CWD Color Combined* Other								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic									
***	Fetal (See Note 3) Abdominal									
Fetal Imaging	Intra-operative (See Note 6) Intra-operative (Neuro.) Laparoscopic									
& Other	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9		
	Small Organ (See Note 5) Neonatal Cephalic	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9		
	Adult Cephalic Trans-rectal							· · · · · · · · · · · · · · · · · · ·		
	Trans-vaginal Trans-urethral									
	Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9		
	Musculo-skel. (Superfic.) Intra-luminal	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9		
Cardiac	Other (spec.) Cardiac Adult Cardiac Pediatric									
	Trans-esophageal (Cardiac) Other (spec.)									
Peripheral Vessel	Peripheral vessel Other (spec.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9		

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription/Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number + 0 3 114

510(k) No.:

Device Name:

MPT4-7 for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	linical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3) Abdominal											
	Intra-operative (See Note 6)		†				 					
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatric		1			-						
	Small Organ (See Note 5)					<u> </u>						
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal							·				
	Trans-urethral							<u>.</u>				
	Trans-esoph. (non-Cardiac)	Р	P	P	P	Р	Note 1	Note 7, 8				
	Musculo-skel. (Convent.)					• • • • • • • • • • • • • • • • • • • •		,				
	Musculo-skel. (Superfic.)											
	Intra-luminal	1		<u> </u>								
	Other (spec.)					.,,						
	Cardiac Adult	Ì										
Cardiac	Cardiac Pediatric							Other				
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note 1	Note 7, 8				
	Other (spec.)					· · · · · · · · · · · · · · · · · · ·						
Peripheral	Peripheral vessel											
Vessel	Other (spec.)	<u> </u>										

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

- Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use/Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number 4013 [17]

510(k) No.:

Device Name: P2-4AA for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	Clinical Application	<u> </u>		Mode	of Opera	tion (*includ	es simultaneous E	B-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)	Î		<u></u>				
	Abdominal	N	N	N	N	N	Note 1	Note 4, 7
•	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							· · · · · · · · · · · · · · · · · · ·
& Other	Pediatric		Ī					
	Small Organ (See Note 5)							
	Neonatal Cephalic		<u> </u>			····		·
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal							•
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)		İ					· · · · · · · · · · · · · · · · · · ·
	Intra-luminal						· ·	
	Other (spec.)	-	-					
	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)					_		
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CER 801.109)

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Division of Reproductive, Abdominal,

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510(k) No.:

Device Name: P2-4AH for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	linical Application				of Opera	ition (*includ	es simultaneous I	3-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal (See Note 3)							
	Abdominal	P	P	P	P	Р	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							······································
Fetal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	Р	P	P	Р	P	Note 1	Note 4, 7
	Trans-rectal							1.000 1,7
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal	,						
	Other (spec.)							
	Cardiac Adult	Р	P	P	Р	P	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	P	P	P	Note I	Note 4, 7
·	Trans-esophageal (Cardiac)							
	Other (spec.)							· · · · · · · · · · · · · · · · · · ·
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription/Use (Per 21 CFR 801.109)	•

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Division of Reproductive, Abdominal,

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510(k) No.:

Device Name: P3-5AC for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			Mode	of Opera	tion (*includ	es simultaneous l	B-mode)
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							· · · · · · · · · · · · · · · · · · ·
	Fetal (See Note 3) Abdominal				_			
•	Intra-operative (See Note 6)	P	P	P	P	P	Note 1	Note 4, 7
		 	₩				-	
Potal Incomina	Intra-operative (Neuro.)	1					 	· · · · · · · · · · · · · · · · · · ·
Fetal Imaging	Laparoscopic	 	<u> </u>					
& Other	Pediatric							<u> </u>
	Small Organ (See Note 5)	 	<u> </u>					
	Neonatal Cephalic		<u> </u>	ļ				
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal				Ì			
	Trans-vaginal							
	Trans-urethral							·
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)	1			·			
	Intra-luminal		† -					
	Other (spec.)	1					-	
	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
Cardiac	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)			·				
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per/21 QFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number __

510(k) No.:

Device Name: P3-7AC for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application		Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
·	Fetal (See Note 3) Abdominal	. P	P	P	P	P	Note 1	Note 4, 7			
Fetal Imaging	Intra-operative (See Note 6) Intra-operative (Neuro.) Laparoscopic							·			
& Other	Pediatric Small Organ (See Note 5)										
	Neonatal Cephalic Adult Cephalic Trans-rectal	P	P	P	P	P	Note 1	Note 4, 7			
	Trans-vaginal Trans-urethral										
	Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.) Musculo-skel. (Superfic.)										
	Intra-luminal Other (spec.)					_					
Cardiac	Cardiac Adult Cardiac Pediatric Trans-esophageal (Cardiac) Other (spec.)	P P	P P	P P	P P	P P	Note 1 Note 1	Note 4, 7 Note 4, 7			
Peripheral Vessel	Peripheral vessel Other (spec.)										

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler, B/Power Doppler, B/Color Doppl

- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

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510(k) Number (1)

510(k) No.:

Device Name: CW 2.0 for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

С	linical Application		Mode of Operation (*includes simultaneous B-mode)									
General (Track I only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)				
Ophthalmic	Ophthalmic											
	Fetal (See Note 3) Abdominal											
	Intra-operative (See Note 6)											
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic											
& Other	Pediatric											
	Small Organ (See Note 5)											
	Neonatal Cephalic											
	Adult Cephalic				P							
	Trans-rectal											
	Trans-vaginal						**					
	Trans-urethral											
	Trans-esoph. (non-Cardiac)					,						
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superfic.)											
	Intra-luminal											
	Other (spec.)											
	Cardiac Adult		ĺ		P			i				
General (Track I only) Ophthalmic Fetal Imaging & Other Cardiac Peripheral	Cardiac Pediatric				P							
	Trans-esophageal (Cardiac)											
	Other (spec.)											
Peripheral	Peripheral vessel				P							
Vessel	Other (spec.)											

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) No.:

Device Name:

CW 4.0 for use with SONOACE X8

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Ī	Mode of Operation (*includes simultaneous B-mode)								
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)			
Ophthalmic	Ophthalmic										
	Fetal (See Note 3) Abdominal Intra-operative (See Note 6)										
Fetal Imaging & Other	Intra-operative (Neuro.) Laparoscopic Pediatric				P						
	Small Organ (See Note 5) Neonatal Cephalic	-									
ı	Adult Cephalic Trans-rectal		-		P						
	Trans-vaginal Trans-urethral						·				
	Trans-esoph. (non-Cardiac) Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic.) Intra-luminal Other (spec.)										
Cardiac	Cardiac Adult Cardiac Pediatric				P P						
	Trans-esophageal (Cardiac) Other (spec.)										
Peripheral Vessel	Peripheral vessel Other (spec.)				P						

N= new indication; P= previously cleared by FDA K063580; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

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Prescription Use (Per 21/CFR 801.109)	•
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510(k) Number <u>KO13'114</u>